Exhibit E

Abbreviated New Drug Application (ANDA) Forms and Submission Requirements

The FDA aspires to assist applicants in developing abbreviated new drug applications (ANDAs). To facilitate the development of an ANDA, agency provides the following resources on ANDA forms and submission requirements.

Please note: Information to assist in the development of generic drug products submitted for FDA review is available in Generic Drug Development (/drugs/abbreviated-new-drug-application-anda-generics/generic-drug-development).

- **ANDA Forms**
  In order to submit a complete ANDA, applicants should review the following forms and prepare all that are required for your specific application.
  - Filing Review of ANDAs MAPP including filing checklist (/media/107325/download) (PDF - 521KB)
  - Form FDA-356h (/media/72649/download): Application to Market a New Drug, Biologic, or Antibiotic Drug for Human Use (PDF - 2.3MB)
  - Instructions for using Form FDA-356h (/media/84223/download) (PDF - 129KB)
  - Instructions for Completing Form FDA 3794 (Generic Drug User Fee Cover Sheet) (/media/132787/download)
  - Form FDA-3674: Certification of Compliance (instructions included) (/media/134964/download)
  - Drug Master Files (/drugs/forms-submission-requirements/drug-master-files-dmfs) (DMFs)
- **Requesting a Pre-Assigned ANDA Number** (/drugs/electronic-submissions-cder/requesting-pre-assigned-application-number)
  Applicants may request a pre-assigned ANDA number ONLY when submitting a new ANDA. If you are converting an established ANDA to eCTD, you MUST use the original ANDA application number. For further guidance, please view Requesting a Pre-Assigned ANDA Number (/drugs/electronic-submissions-cder/requesting-pre-assigned-application-number) or email CDERAPPNUMREQUEST@fda.hhs.gov (mailto:CDERAPPNUMREQUEST@fda.hhs.gov).

- **Electronic Submissions**
  The FDA no longer accepts paper ANDA submissions. All ANDA submissions MUST be in eCTD format. eCTD submission sizes 10 GB or less must use the FDA Electronic Submission Gateway (/drugs/forms-submission-requirements/electronic-regulatory-submission-and-review) (ESG). If an eCTD submission is greater than 10 GB, it may be submitted via physical media (DVD/USB Drive) to the CDER Document Room or via ESG. Please see the guidance for industry "Transmitting Electronic Submissions Using eCTD specifications (/media/76812/download)" for details. This document and other eCTD related guidance and specifications are available on the FDA eCTD website (/drugs/electronic-submissions-cder/electronic-common-technical-document-ectd).

  For the submission of Form FDA 3500A reports (15-day Alert Reports and Periodic Adverse Drug Experience Reports) to ANDAs, continue to send these to the following address:
  Central Document Room
  5901-B Ammendale Road
  Beltsville MD 20705-1266

- **Question-Based Review (QbR)**
  QbR is a science- and risk-based Chemistry, Manufacturing, and Controls (CMC) evaluation that focuses on critical pharmaceutical attributes essential for ensuring generic drug product quality.

  - QbR for CMC evaluation of an abbreviated new drug application (ANDA) (/drugs/abbreviated-new-drug-application-anda-generics/question-based-review-cmc-evaluations-andas)
  - QbR for Sterility Assurance Evaluation (Product Quality Microbiology Review) of ANDAs (/drugs/abbreviated-new-drug-application-anda-generics/question-based-review-sterility-assurance-evaluation-product-quality-microbiology-review-andas)
  - QbR for Sterility Assurance of Aseptically Processed Products (PDF - 25KB) (/media/88696/download)
  - Labeling Questions for Sponsors (/drugs/how-drugs-are-developed-and-approved/labeling-questions-sponsors)

- **Summary Tables**
  These summary tables provide a standard format for data to be in an ANDA in a concise format consistent with current recommendations. See the tables for instructions.

  - Model Bioequivalence Data Summary Tables (PDF - 185KB) (/media/75081/download)
    A detailed content and format information resource for generic drug applicants submitting ANDAs to FDA

- BCS-Based Study Summary and Formulation Tables (PDF - 191KB) (/media/148433/download)
- Bioequivalence Summary Tables for In Vitro Feeding Tube Testing (PDF - 407KB) (/media/98853/download)
- Comparative Clinical Endpoint Bioequivalence Study Summary Tables (PDF - 845KB) (/media/119053/download)
- Topical Dermatologic Corticosteroids In Vivo Bioequivalence Study Summary Tables and SAS Transport Formatted Tables for Dataset Submission (PDF - 670KB) (/media/87599/download)
- In Vitro Binding Bioequivalence Study Summary Tables and SAS Transport Formatted Tables for Dataset Submission (PDF - 231KB) (/media/86552/download)
- Summary Tables for the Listing and Characterization of Impurities and Justification of Limits in Drug Substance and Drug Products (PDF - 60KB) (/media/87722/download)
  (consistent with the recommendations delineated in the Guidances for Industry ANDAs: Impurities in Drug Substances (/media/77324/download) and ANDAs: Impurities in Drug Products (/media/71351/download))
- Bioequivalence Summary Tables For Aqueous Nasal Spray Products (PDF - 1.1MB) (/media/78375/download)
- Pharmacy Bulk Package Sterility Assurance Table (PDF - 19KB) (/media/86126/download)
- Irritation/Sensitization/Adhesion Study Summary Tables (PDF - 934B) (/media/119055/download)
- Bioequivalence Summary Tables For Pressurized Metered Dose Inhaler Products (PDF - 331KB) (/media/119054/download)

Generic Drug Regulatory Resources

- Product-Specific Guidances for Generic Drug Development (/drugs/guidances-drugs/product-specific-guidances-generic-drug-development)
- Laws Enforced by the FDA (/drugs/abbreviated-new-drug-application-anda-generics/generic-drug-review-dashboard-report)
- Generic Drug User Fee Amendments (GDUFA) (/industry/fda-user-fee-programs/generic-drug-user-fee-amendments)
- Code of Federal Regulations (https://www.ecfr.gov/cgi-bin/ECFR?page=browse) (CFR)

- Federal Register (https://www.federalregister.gov/) (FR)
- CDER FOIA Electronic Reading Room (/drugs/guidance-compliance-regulatory-information/cder-foia-electronic-reading-room)

Learn More

- **Generic Drugs Program (/generic-drugs)**
- **Industry Resources (/drugs/generic-drugs/industry-resources)**

Contact FDA

Potential applicants are encouraged to contact the FDA Generic Drugs Program with questions at any point in their development and ANDA preparation processes.

For inquiries related to ANDAs pending filing review and the status of pending suitability petitions, please email ANDAFiling@fda.hhs.gov (mailto:ANDAFiling@fda.hhs.gov).

If you have specific questions regarding the development of a generic drug product not yet submitted in an abbreviated new drug application (ANDA), please submit a controlled correspondence (/industry/generic-drug-user-fee-amendments/fda-posts-final-guidance-industry-controlled-correspondence-related-generic-drug-development) by email to genericdrugs@fda.hhs.gov (mailto:genericdrugs@fda.hhs.gov).

If you have a general question about generic drugs, please email druginfo@fda.hhs.gov (mailto:druginfo@fda.hhs.gov).

If you have a question regarding an ANDA for which you are the applicant or authorized representative, please contact the regulatory project manager assigned to the application.

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